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EXAMINER	
LUCAS, ZACHARIAH	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 04/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/938,406	LOWELL ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *2,5,8 and 9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,6,7 and 10-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Claims

1. As indicated by the Applicant in the Response to the Restriction Requirement filed on October 14. 2003 (the Response), claims 1-19 are pending in the application, claims 19-32 having been cancelled by preliminary amendment. Currently, claims 1-18 are pending in the application.

Election/Restrictions

2. Applicant's election with traverse of Group II in the Response is acknowledged. The traversal is on the ground(s) that the Examiner may not reject claims on the basis of representing independent and distinct inventions. This is not found persuasive because no claims have been rejected on this basis. While the Restriction requirement does require the Applicant to elect a particular invention from the independent inventions in the claims, this is not a rejection of the claims. Nor is the Office, by requiring the restriction requirement refusing to examine the broad claims. In cases such as the present case, the broadest claims will be examined as per the USPTO linking claim practice, described in MPEP § 809. Because the no claims have been rejected for misjoinder, and because the Applicant's other concerns appear to be satisfied by the PTO's linking claim practice, the Applicant's traversal not found persuasive.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 1, 3, 4, and 6, 7, and 10-18 are pending and under consideration in the present application. The claims are under consideration to the extent that they read on the elected

inventions (wherein the exogenous hydrophobic material comprises a C8-C18 fatty acyl group). Claims 2, 5, and claims 8, and 9 (dependant on claim 5) are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the Response.

It is noted that claims 8 and 9 were previously indicated to be part of Group II in the restriction requirement. However, while the Examiner apologizes for the inconvenience, it is noted that these claims depend from the non-elected claims, and thus do not represent the elected invention. These claims are therefore also withdrawn as to non-elected inventions.

Specification

4. The disclosure is objected to because of the following informalities: on page 6, line 3, the term "Atni-HIV" should read --anti-HIV--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 3,4, 6, 7, 10-12, and 16-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims read on compositions comprising an antigen and an exogenous hydrophobic fatty acyl group or lauroyl material, and "complexed with

said antigen, a composition comprising proteosomes, bioadhesive nanoemulsions, or both." It is unclear what is meant by this phrase. In particular, it is unclear how the antigen is complexed with a composition comprising the proteosomes or nanoemulsions, or if the Applicant intended that the antigens be complexed with the proteosomes or nanoemulsions themselves. Clarification is required.

For the purposes of this action, the claims are being read as requiring the antigens to be complexed with the proteosome or nanoemulsion of the claims.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1, 3, 4, 6, 7, and 10-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for vaccine compositions against certain pathogenic organisms (i.e. using vaccine antigens known in the art to be effective), does not reasonably provide enablement for the full scope of the claims. I.e., the Applicant has not demonstrated that any antigen capable of raising a neutralizing immune response, in particular vaccines comprising the antigens indicated as the preferred viral antigens- those which target HIV-1, would be effective vaccine antigens. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The claims are broadly drawn to vaccine compositions comprising

any pathogenic organism, a C8-18 fatty acyl groups, and wherein the antigen has an endogenous hydrophobic sequence of between 3 and 50 non-polar or uncharged amino acids. Claims 7 and 18 further describe the vaccine composition as, respectively, comprising a viral envelope protein as an antigen, and as against a pathogenic organism causing a sexually transmitted disease. The specification further indicates that the preferred antigen is an HIV-1 antigen. See, page 8, lines 9-11, and pages 20-24. The term vaccine is understood in the art to mean a composition capable of inducing a prophylactic or therapeutic effect against a target pathogen. See e.g., definition of "vaccine" in any of Stedman's Medical Dictionary, the On-line Medical Dictionary, or Merriam-Webster's Online Dictionary, 10th Edition. Thus, the claims read on a composition capable of inducing prophylaxis or amelioration of an infectious disease comprising an antigen, a hydrophobic material, and a proteosome or nanoemulsion.

In making a determination as to whether an application has met the requirements for enablement under 35 U.S.C. 112 ¶ 1, the courts have put forth a series of factors. See, In re Wands, 8 USPQ2d 1400, at 1404 (CAFC 1988); and Ex Parte Forman, 230 U.S.P.Q. 546 (BPAI 1986). The factors that may be considered include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. Id. While it is not essential that every factor be examined in detail, those factors deemed most relevant should be considered.

In the present case, the Applicant has demonstrated that anti-HIV-1 antibodies have been induced in various rodents through administration of embodiments of the claimed composition.

See e.g., pages 43-44. Thus, the Applicant appears to be enabled for immunogenic compositions against antigens generally. However, the Applicant has not demonstrated that the claimed compositions are able to induce a protective response against HIV-1. While the Applicant demonstrated that administration of the claimed composition with an anti-HIV antigen was able to induce antibodies in mice, the Applicant did not demonstrate that the mice were protected from later exposure to HIV. Further, it is known in the art that, with respect to HIV, animal models are not predictive of an immunogenic compositions efficacy in humans. See e.g., Feinberg et al., Nature Medicine 8(3): 207-10 (teaching on page 209 that, while animal models are an invaluable resource in developing HIV vaccines, an animal model is not predictive of the efficacy of a vaccine in humans). Thus, while the Applicant has presented data indicating that the claimed composition would be an effective immunogenic compositions, the data presented is not sufficient to demonstrate that the claimed compositions would make effective vaccines.

The art surrounding the claimed invention further supports the finding of a lack of an enabling disclosure. The art teaches that those in the art have, to date, been unable to produce an effective therapeutic vaccine against HIV. See e.g., Kaur et al., Topics in HIV Medicine 11(3): 76-85, esp. page 85. Each of Kaur and Feinberg illustrate challenges faced by those in the art, and demonstrate both the complexity and the unpredictability involved in the development of HIV vaccines.

Further, the lack of success in developing HIV vaccines is found even though the art demonstrates knowledge of those within it of antigens that produce neutralizing antibodies. See e.g., Vancott et al., J Immunol Methods 183: 103-17, and Catasti et al., J Biol Chem 271(14): 8236-42 (each disclosing HIV-1 antigens known as targets for HIV-1 neutralizing antibodies).

Thus, the art establishes that knowledge in the art of pathogen antigens capable of inducing the production of a neutralizing antibody is not sufficient to demonstrate that the antigen would be an effective vaccine antigen.

The teachings in the art therefore demonstrate that the ability to induce the production of a neutralizing antibody is not sufficient to demonstrate vaccine efficacy, and that the art of HIV-1 vaccination is complex and unpredictable. In view of the absence of evidence by the Applicant that the claimed compositions would be effective as vaccines, the Applicant is not found to have provided an enabling disclosure for vaccines according to the claimed invention, although they would be enabled for immunogenic compositions comprising the indicated antigen, fatty acid, and proteosome or nanoemulsion.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1, 3, 4, 6, and 10-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Lowell et al., Science 240(4853): 800-02. The claims have been described above. Lowell teaches the combination of a lauroyl containing hydrophobic material with an antigenic peptide

comprising an endogenous hydrophobic sequence, and a proteosome. See, abstract, page 800, and notes 11 and 12 (page 802). The reference therefore teaches that claimed compositions.

11. Claims 1, 3, 4, 6, and 10-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Lowell et al., U.S. Patent 5,726,292 (the 292 patent). The claims have been described above. The 292 patent claims a construct comprising a protein, a hydrophobic anchor, including where the anchor is a lauroyl moiety, and a proteosome. Claims 1 and 5. The patent's specification indicates that the antigens used in the claimed constructs may include hydrophobic sequences (column 13, lines 44-50). Thus, the patent teaches the making and use of constructs according to the presently claimed inventions. Further, the reference also indicates that proteosome associated antigens are capable of inducing mucosal and respiratory responses, and that mice vaccinated with such constructs where given protection- thereby indicating that the constructs would be effective in inducing neutralizing antibodies. See e.g. Columns 19-20. Thus, it appears that the functional language of the present claims merely illustrates an inherent property of the invention claimed by the 292 patent.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 7 and 18 are rejected under 35 U.S.C. 103(a) as being obvious over the 292 patent as applied against claims 1, 3, 4, 6, and 10-17 above. Claims 7 and 18 further limit the claimed constructs to embodiments wherein the protein antigen comprises a viral antigen or an antigen of a mucosally- or sexually transmitted disease. The 292 patent suggests the use of the claimed compositions for the induction of anti-HIV immune responses. Columns 17-18. It would therefore have been obvious to make constructs comprising this protein antigen. It is noted that the Applicant further requires that the claimed composition is capable of inducing the production of neutralizing antibodies. However, this is merely a recitation of an intended use, and does not structurally distinguish the claimed composition from that of the prior art. The claims are therefore rejected as obvious over the teachings of the 292 patent.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter

disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

14. Claims 7 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lowell as applied to claims 1, 3, 4, 6, and 10-17 above, and further in view of Vancott et al., J Immunol Methods 183: 103-17. The claims have been described above, as have the teachings of Lowell and the 292 patent. Lowell does not teach the use of a viral antigen in the constructs described therein. However, the Vancott reference teaches that the HIV-1 gp160 protein is capable of inducing a neutralizing immune response. As Lowell teaches that the antigen/hydrophobic group/proteosome constructs are useful in the generation of immune responses against antigenic peptides and proteins. It would therefore have been obvious to those in the art to use the antigen delivery/adjuvant construct of Lowell as a vehicle for the delivery of the gp160 antigens disclosed in Vancott. The motivation to do so is that Lowell teaches that the use of the construct as a delivery vehicle acts as an adjuvant to the induction of an immune response. As Lowell teaches that the construct was useful for inducing responses against certain antigens, and

suggests the use for vaccines in general, those in the art would have had a reasonable expectation of success in the use of the Lowell construct in a composition comprising the Vancott antigens.

15. Claims 1, 3, 4, 6, 7, 10, 11, 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of the 292 patent, Lowell, or Lowell in view of Vancott as applied above, and further in view of WO 95/11700. The claims read on the vaccine compositions disclosed above wherein the antigen and hydrophobic fatty acyl are complexed with a nanoemulsion. The references other than the WO document have been described above. They do not teach the use of a nanoemulsion rather than, or in addition to, the proteosomes. The WO document teaches the use of submicron emulsions (nanoemulsions) as adjuvants for vaccines. Abstract. The reference teaches that the emulsions can be used alone, or in combination with other adjuvants (page 4), that the emulsions can be used for the induction of mucosal immunity (page 5), and that the antigens may be complexed to the surface of the emulsion in a similar manner to that disclosed in the 292 patent and Lowell with respect to proteosomes (claims 1, 13-17). Thus, it would have been obvious to those in the art to have used the nanoemulsion either in combination with, or as an alternative to the proteosomes of the other references.

Double Patenting

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 1, 3, 4, 6, 7, 10-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 5, 7, and 8 of U.S. Patent No. 5,726,292. Although the conflicting claims are not identical, they are not patentably distinct from each other because the constructs claimed and described in the claims of the patent appear to include the currently claimed compositions. In particular, the specification of the patent indicates that the antigens used in the claimed constructs may include hydrophobic sequences (column 13, lines 44-50). Thus, the patent suggests the teaching and use of proteosomes according to the present claimed inventions. Further, the reference also indicates that proteosome associated antigens are capable of inducing mucosal and respiratory responses, and that mice vaccinated with such constructs where given protection- thereby indicating that the constructs would be effective in inducing neutralizing antibodies. Thus, it appears that the functional language of the present claims merely illustrates an inherent property of the invention claimed by the 292 patent. Furthermore, the patent also suggests the making of constructs with the HIV gp160 protein. Columns 17-18. Thus, it would have been obvious to those in the art to make constructs according present claims 7 and 18. Claims 1, 3, 4, 6, 7, 10-18 are therefore rejected as obvious variations of the indicated claims of the 292 patent.

18. The above rejection is, in part, based on the specification of a previously issued patent, rather than the claims. In support of the use of this material, the examiner notes the following excerpt from MPEP section 804:

> When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. This does not mean that one is precluded from all use of the patent disclosure.
>
> The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. In re Boylan, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. In re Vogel, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in Vogel recognized "that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim," but that one can judge whether or not the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. According to the court, one must first "determine how much of the patent disclosure pertains to the invention claimed in the patent" because only "[t]his portion of the specification supports the patent claims and may be considered." The court pointed out that "this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined."

Thus, the courts have held that it is permissible to use the specification in determining what is included in, and obvious from, the invention defined by the claim on which the rejection is based. This is true even where elements are drawn from the specification describing the claimed invention which are not elements in the claim itself.

Conclusion

19. The following prior art reference is made of record and considered pertinent to applicant's disclosure. However, while relevant they are also not used as a basis for rejection for the stated reasons.

> Kaminski et al., 94th General Meeting of the American Society for Microbiology, 1994, Page 155, abstract E-70. This reference teaches the formulation of a viral protein with a proteosome for the induction of an immune response. However, the reference does not

teach that the compositions comprise a hydrophobic component other than the proteosome.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner

JAMES HOUSEL 4/2/04
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